



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

FEB 16 2000

1736 '00 FEB 29 P2:11

Mr. Warren Lancaster
VP North America
Novogen, Inc.
One Landmark Square, 2nd Floor
Stamford, Connecticut 06901

Dear Mr. Lancaster

This is in response to your letter of February 1, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Novogen, Inc. is making the following statement, among others, for the product "**Trinovin**":

"Men on traditional Asia, Latin America and Mediterranean diets, which are high in isoflavone consumption, generally maintain normal prostate health later in life than men on a typical American diet"

"Helps maintain normal urination patterns at night later in life"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The claims that you are making for this product suggest that it is intended to treat, cure, prevent, or mitigate disease, namely, prostate disorders in older men. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

975-0163

LET 341

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200

FDA, New England District Office, Compliance Branch, HFR-NE240

cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFS-22 (CCO)

HFS-456 (r/f, file)

HFS-450 (r/f, file)

HFD-310

HFD-314 (Aronson)

HFS-605

HFV-229 (Benz)

GCF-1 (Barnett, Nickerson, Dorsey)

f/t:rjm:HFS-456:2/11/00:69114.adv:disc44

February 1, 2000

69114

Dr. Elizabeth Yetley
Director, Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

Dear Dr Yetley:

As per 21 CFR §101.93(a), Novogen, Inc. is making this notification that we are marketing a dietary supplement that bears statements listed in section 403(r)(6) of the Food, Drug and Cosmetic Act.

Name/Address of Distributor:

Novogen, Inc.
One Landmark Square, 2nd Floor
Stamford, CT 06901

Name of Dietary Supplement:

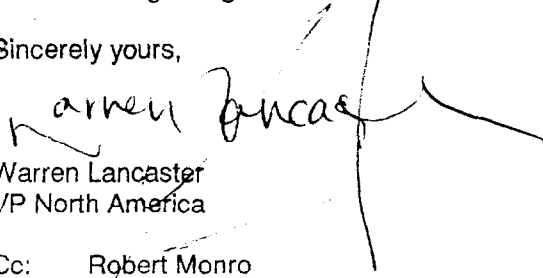
Trinovin

Text of Statements being made:

- Maintains (assists, promotes) free urinary flow, normal prostate function (health) and quality of life.
- Men on traditional Asian, Latin American and Mediterranean diets, which are high in isoflavone consumption, generally maintain normal prostate health later in life than men on a typical American diet.
- Helps maintain normal urination patterns at night later in life.

Please note that our labeling does contain the appropriate disclaimer as required under 21 CFR §101.93(b). Please contact the undersigned at (203) 327-1188, if you have any questions, or comments regarding this notification.

Sincerely yours,


Warren Lancaster
VP North America

Cc: Robert Monro
Mark Waring